

Customer No. 31013
Atty. Docket No.: 055474/00007

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Patrick J. Kelly et al. Group Art Unit : 3626
Serial No.: 10/620,233 Examiner: C. Luke Gilligan
Filed: July 14, 2003
For: **METHOD AND SYSTEM FOR EARLY DETECTION OF DISEASE**

May 9, 2008

APPEAL BRIEF

Mail Stop APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal from the final rejection of claims 1-20 in the above-referenced patent application. A Notice of Appeal in this application was received by the U.S. Patent and Trademark Office on October 9, 2007. This Appeal Brief is being filed on May 9, 2008, within seven (7) months from the date of receipt of the Notice of Appeal. A separate Petition for a Five Month Extension of Time is being filed herewith (including authorization to charge the extension fee to Deposit Account No. 50-0540).

Please charge the amount of \$255.00 to cover the fee under 37 CFR 41.20(b)(2) for filing a brief in support of an appeal to Deposit Account No. 50-0540. Please charge any fee deficiency and credit any overpayment to Deposit Account No. 50-0540. A duplicate copy of this page is attached.

REAL PARTY IN INTEREST

The real parties in interest in this appeal are inventors Patrick J. Kelly, M.D. and Charles J. Conroy, each of New York, New York.

RELATED APPEALS AND INTERFERENCES

Applicants are not aware of any related appeals or interferences which directly affect, or are directly affected by, or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1-20 are pending in this application. Independent claims 1, 13 and 20 and dependent claims 2-10, 14-15 and 18-19 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Ralston et al., U.S. Patent No. 6,398,454 (hereinafter "Ralston"), in view of Dubois et al., *Source Localization Following Permanent Transperineal Prostate Interstitial Brachytherapy Using Magnetic Resonance Imaging*, INT. J. RADIATION ONCOLOGY BIOL. PHYS., Vol. 39, No. 5, 1037-1041 (1997) (hereinafter "Dubois"). Dependent claims 11-12 and 16-17 stand finally rejected under 35 U.S.C. §103(a) as being obvious over Ralston in view of Dubois and further in view of Pinard et al., 5,934, U.S. Patent No. 5,480,769 ("Pinard").

This is an appeal from the final rejection of claims 1-20 as set forth in the final Office Action mailed April 9, 2007. The Claims Appendix annexed hereto lists claims 1-20 under appeal.

STATUS OF AMENDMENTS

Applicants appeal the final rejection of independent claims 1, 13 and 20 and dependent claims 2-10, 14-15 and 18-19 set forth in the final Office Action mailed April 9, 2007 (hereinafter the "Final Office Action"). On August 24, 2007, Applicants filed a Response to Final Office Action Mailed April 9, 2007. The Response did not present any claim amendments.

In an Advisory Action mailed September 13, 2007, the Reply was entered and made of record for consideration on appeal -- the Examiner maintaining all of the outstanding claim rejections.

Applicants filed a Notice of Appeal on October 9, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in detail in the present application, Applicants' claimed invention is directed to embodiments of a system and method to allow an asymptomatic member of the general public to access a scheduling service provider and arranged a screening MRI without a medical referral. After a user profile is completed and accepted by the scheduling service provider, an appointment for an abbreviated MRI can be scheduled with a participating MRI facility or MRI screening center. Alternatively, low cost purpose built MRI screening units which can be conveniently located and available for the general public may be utilized.

According to the claimed invention, the scheduling service provider can increase the percentage utilization of the existing MRI facilities and increase the availability of MRI scanning to the general public at a reduced cost.

According to various exemplary embodiments of the claimed invention, the consolidation of unused capacity of diagnostic MRI facilities for utilization by the general public and the changing the procedural paradigms for screening, as opposed to using MRI for diagnostic purposes, can create economics of scale by significantly reducing scanning time and maximizing throughput. *Specification* at ¶ [0014]¹. In such exemplary embodiments, the cost of a screening examination can be greatly reduced compared to the costs of diagnostic MRI examinations. *Id.* This can reduce the cost of a screening scan according to claimed invention to

¹ References to the present Specification are to its published version, *i.e.*, United States Patent Application Publication No. 20050091079.

10%-15% of the cost of a diagnostic MRI. *Id.* For example, a screening MRI procedure (*e.g.*, a Type 2 scan) can be performed in approximately three to five minutes, compared with one hour or longer to perform a diagnostic MRI procedure. Nonetheless, a T2 MRI scan can detect abnormalities as small as 5 mm in diameter. *Id.*

Thus, according to the claimed invention, screening can be made available to a much greater proportion of the general population which at the present time has a very limited access. *Specification* at ¶ [0015]. Moreover, the value of such a screening scan can be much greater in asymptomatic people as the early detection of pathology in these individuals has a better chance of actually leading to a potentially curative procedure. *Id.*

Illustrating the fact that the claimed invention allows an asymptomatic member of the general public to access a scheduling service provider and arrange a screening MRI on their own, at their own personal initiative, and without having any pre-existing medical conditions motivating the MRI, the Specification offers how it is within the scope of the invention to perform such MRI screening in a variety of casual and wholly non-medical venues:

Finally, a purpose built MRI screening unit which could be located at public gathering places such as malls, airports, etc. also are within the scope of the method and system according to an embodiment of the present invention. Such an alternative could include, for example, a purpose built MRI unit (*e.g.*, for screening procedures instead of diagnostic purposes), a metal detection alarm, an interactive screening history questionnaire, a credit card scanning unit, an Internet connection for billing and data acquisition, an on-board or networked computer program which would compare each scan to a normative database and an output method which would inform the user of the results of the scan.

Specification at [0031] (emphasis added).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues on appeal are two-fold, namely: (i) whether independent claims 1, 13 and 20 and dependent claims 2-10, 14-15 and 18-19 are patentable under 35 U.S.C. §103(a) over Ralston and Dubois; and (ii) whether dependent claims 11-12 and 16-17 are patentable under 35 U.S.C. §103(a) in view of Ralston, Dubois and Pinard.

ARGUMENT

I. Patentability Under 35 U.S.C. §103

A. Legal Framework – The Case For Obviousness.

The case for obviousness under 35 U.S.C. §103 is a procedural tool of examination, and requires that the Examiner initially produce evidence sufficient to support a ruling of obviousness. *See In re Piasecki*, 745 F.2d 1468 [223 USPQ 785] (Fed. Cir. 1984); *see also, In re Oetiker*, 977 F.2d 1443 [24 USPQ2d 1443] (Fed. Cir. 1992). If the Examiner does not make a case, the applicant is under no obligation to submit evidence of non-obviousness. *See In re Piasecki*, 745 F.2d at 1472; *In re Oetiker*, 977 F.2d at 1445; *see also*, MPEP §2142.

In determining obviousness, one must then determine whether, in light of the teachings found in one or more prior art references, the technological development recited in the claim would have been obvious at the time of the invention to one of ordinary skill in the field of the invention having knowledge of the relevant prior art. 35 U.S.C. § 103. The relevant factors in determining obviousness are: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of invention; (3) the differences between the invention and the prior art; and (4) objective evidence of nonobviousness such as long-felt need, commercial success, the failure of others, or copying. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Brown &*

Williamson Tobacco Corp. v. Phillip Morris Inc., 229 F.3d 1120, 1124-25 (Fed. Cir. 2000); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1351 (Fed. Cir. 1998).

B. The Examiner Has Failed To Establish A Case For Obviousness In The Rejection Of Independent Claims 1, 13 And 20 And Dependent Claims 2-10, 14-15 And 18-19 Over Ralston In View Of DuBois

The Examiner admits that the Ralston reference does not teach scheduling an abbreviated MRI procedure designed for an asymptomatic individual. Final Office Action at ¶ 5. The Final Office Action relies solely on Dubois for the proposition that “abbreviated MRI procedures for asymptomatic individuals along with providers capable of performing them are old and well known in the art.” Final Office Action at 3. Citing to Dubois the Examiner states “(see page 1 in particular and note that an abbreviated MRI procedure was utilized for the postimplant evaluation).” *Id.*

In the subsequent Advisory Action, the Examiner reiterated this position, and explained why the Response to Final Office Action filed on August 24, 2007 allegedly did not place the application in condition for allowance, based on Dubois’ description of treatment of post-implant prostate cancer patients:

In the remarks filed 8/24/07, Applicants argue in substance that the MRI procedure taught by Dubois is no[t] [sic] an abbreviated MRI procedure designed for an asymptomatic individual. In response to Applicants’ arguments, the Examiner respectfully maintains that, given the broadest reasonable interpretation to one of ordinary skill in the art, the MRI procedure taught by Dubois falls within the scope of the claimed “abbreviated MRI procedure designed for an asymptomatic individual.” First, Dubois clearly identifies the MRI procedure as an “optimized and abbreviated MR scanning sequence” (see page 1). Therefore, it is unclear to the Examiner how one could argue that Dubois does not teach an abbreviated MRI procedure. Secondly, the Examiner was unable to locate any specific definition in Applicants’ specification defining the term “asymptomatic individual.” However, within the context of the specification it appears that the term is used to describe an individual who doesn’t have any known symptoms that would require an MRI to diagnose. Similarly, the only purpose of the

abbreviated MRI procedures of Dubois is to evaluate the brachytherapy implant. They are not, on the other hand, designed to evaluate a particular symptom of the patient.

Advisory Action at 2.

It simply is not correct that a post-implant prostate cancer patient is an asymptomatic individual as recited in the pending claims. The Examiner makes two points, both addressed to a single element of each finally rejected claim: “an abbreviated MRI procedure designed for an asymptomatic individual.”² First, the Examiner asserts that “the only purpose of the abbreviated MRI procedures of Dubois is to evaluate the brachytherapy implant. They are not, on the other hand, designed to evaluate a particular symptom of the patient.” Second, that Dubois teaches “an optimized and abbreviated MRI scanning sequence” as claimed. Advisory Action at 2.

As to the first point, the Examiner concludes that because the purpose of the specialized MRI procedures in Dubois was not to evaluate a particular symptom of the patient, the prostate cancer patients in Dubois were “asymptomatic.” That makes no sense, inasmuch as it is being done after a cancer treatment – and thus performed on a clearly symptomatic individual. As to the second, Dubois teaches a specialized and particularized MMI procedure, specifically developed to improve upon prior post-implant follow-up imaging, and specifically designed to perform dosimetric evaluation. Indeed, Dubois states: “[t]he cost of the optimized and abbreviated MR scanning sequence used in this study is comparable to a pelvic CT scan” (emphasis added). Dubois at Abstract.

² This is the phrasing in claim 1. Independent claims 13 and 20 style it “an abbreviated MRI-based health care screening procedure designed for an asymptomatic individual.”

Applicants respectfully assert that Ralston and Dubois do not teach the method, system or article of manufacture of independent claims 1, 13 and 20, or of dependent claims 2-10, 14-15 and 18-19, which each recite scheduling an abbreviated MRI procedure designed for an asymptomatic individual via a scheduling service, determining if the abbreviated MRI procedure can be authorized, and scheduling the abbreviated MRI procedure with a provider capable of performing the abbreviated MRI procedure, wherein the scheduling includes selecting a location and an unused time slot for the abbreviated MRI procedure available between scheduled diagnostic MRI procedures at one of a predetermined set of existing procedure facilities affiliated with the scheduling service as a function of location and time parameters of a user and an availability of the predetermined set of procedure facilities.

As Applicants repeatedly argued to the Examiner in the telephonic interview of June 27, 2007, as well as in the Response to Final Office Action, Dubois does not address members of the general public looking to schedule a health care screening scan. Use of MRI imaging for the evaluation of dosimetric data for a prostate cancer brachytherapeutic implant is not the claimed “MRI-based health care screening for asymptomatic individuals.” Further, Dubois does not address asymptomatic individuals, *i.e.*, people who exhibit no symptoms of disease. Dubois addresses prostate cancer patients. In fact, Dubois addresses prostate cancer patients with a permanently implanted radioactive source near their prostate gland, and how to collect accurate dosimetric data relating to such implant. As Dubois succinctly states, the purpose of its study was follow-up evaluation of prostate cancer afflicted medical patients who have undergone completed brachytherapy implant procedures:

Purpose: Dosimetric evaluation of completed brachytherapy implant procedures is crucial in developing proper technique and has prognostic implications. Accurate definition of the prostate gland and localization of the implanted radioactive sources are

critical to attain meaningful dosimetric data. Methods using radiographs and CT accurately localize sources, but poorly delineate the prostate gland. MRI has been recognized as a superior imaging modality in delineating the prostate gland, but poor in localizing sources due to lack of source visibility. The purpose of this study was to optimize the visualization of sources using MRI and compare to CT derived source localization.

Dubois at Abstract.

Dubois' methods have "prognostic implications" for such patients (*see* Dubois at Abstract). Accurate dosimetric evaluation of completed implants is crucial in developing proper technique and determining potential efficacy. *Id.* at 1 (Introduction). Therefore, the prostate cancer patients studied in Dubois were clearly not asymptomatic members of the general public, as recited in the claimed invention. On the contrary, in the Dubois study "[t]he CT and MRI scans of 20 consecutive patients who had received TRUS-guided permanent transperineal interstitial prostate ¹²⁵Iodine or ¹⁰³Palladium brachytherapy were evaluated using an in-house dosimetry system." Dubois at Abstract. Dubois is directed to implant evaluation in such patients. *Id.* Such evaluation is crucial in developing proper technique (*i.e.*, for proper placement of the radioisotope containing brachytherapeutic source) and has prognostic implications. *Id.*

Thus, Dubois describes a follow-up study conducted on prostate cancer patients who have been permanently implanted with a radioactive source. Dubois' aim was to develop techniques to visualize both the implant and the prostate gland in a single image, whereas prior methods only focused on imaging the implant. Dubois at 1 (Introduction). Multiple MRI scanning techniques were attempted until a specific and specialized MRI sequence was developed to visualize both the prostate gland and the implant. Dubois at Abstract (Methods and

Materials). The Dubois technique that was finally decided upon used a pelvic coil to perform MRI exams using a specialized sequence.

In the Advisory Action the Examiner appears to introduce some confusion as to the meaning of the term “asymptomatic.” In particular, the Examiner states “it appears that the term is used to describe an individual who doesn’t have any known symptoms that would require an MRI to diagnose.” This term’s meaning is well known, and not subject to creative recasting:

asymptomatic *adj.* Neither causing nor exhibiting symptoms of disease.

The American Heritage Dictionary, Third Edition (Houghton Mifflin Company 1994).

Prostate cancer patients very much do exhibit symptoms of a disease – they have prostate cancer! The Dubois patients further exhibit the symptoms of a nuclear medicine based treatment for that disease – they have a radioactive source permanently implanted adjacent to their prostate. A post-operative patient is not an asymptomatic individual! That is why he requires follow-up as opposed to the generic “abbreviated MRI-based health care screening procedures” as claimed.

Additionally, the MRI examinations in Dubois were not scheduled by the individual, on his own initiative, for general health care screening – the Dubois MRI examinations were scheduled and performed by oncology researchers for the purpose of accurate dosimetric evaluation of completed implants, which is crucial in developing proper technique and determining potential efficacy. Dubois at 1 (Introduction).

In contrast to the asymptomatic individual of the claimed invention, in Dubois, in order to evaluate the dosimetry of an *in vivo* radioactive implant, it was desirable to do follow-up imaging. Dubois and his co-oncologists developed an MRI technique precisely for such follow-up imaging. Dubois’ technique has nothing at all to do with the claimed abbreviated MRI-based

health care screening procedure designed for an asymptomatic individual. It involved a specialized and particularized MRI procedure developed for post-implant prostate cancer patients so as to allow visualization of both the implant and the prostate gland. Thus, for example, it does not include a generic “T2 type MRI scan” as recited in dependent claims 2 and 18. Applicants respectfully assert that Ralston and Dubois do not teach the claimed invention, whether alone or in combination.

C. The Examiner Has Also Failed To Establish A Case For Obviousness In The Rejection Of Dependent Claims 11-12 and 16-17 Over Ralston In View Of DuBois And Further In View of Pinard

In the Final Office Action the Examiner rejected claims 11-12 and 16-17 based on Ralston and Dubois, and further in view of Pinard. Given the severe deficiencies of Ralston and Dubois as references against the novel features of independent claims 1, 13 and 20 as demonstrated above, Applicants respectfully assert that the Examiner cannot establish a case for obviousness based on the combination of Ralston and Dubois and Pinard with respect to claims 11-12 and 16-17 which variously depend therefrom. Accordingly, the final rejection of dependent claims 11-12 and 16-17 under 35 U.S.C. §103(a) should also be reversed.

CONCLUSION

For the reasons advanced above, Applicants respectfully submit that claims 1-20 are allowable over the cited references. Applicants therefore respectfully request that the rejections of (i) independent claims 1, 13 and 20 and dependent claims 2-10, 14-15 and 18-19 under 35 U.S.C. §103(a) over Ralston and Dubois; and (ii) dependent claims 11-12 and 16-17 under 35 U.S.C. §103(a) in view of Ralston, Dubois and Pinard, all be reversed.

Respectfully submitted,

Date: May 9, 2008

/Aaron S. Haleva/

Jonathan S. Caplan
Reg. No. 38,094
Aaron S. Haleva
Reg. No. 44,733
KRAMER LEVIN NAFTALIS & FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036
(212) 715-9100

CLAIMS APPENDIX

1. A method for health care screening, comprising: contacting a scheduling service; scheduling an abbreviated MRI procedure designed for an asymptomatic individual via the scheduling service; determining if the abbreviated MRI procedure can be authorized; and scheduling the abbreviated MRI procedure with a provider capable of performing the abbreviated MRI procedure; wherein the scheduling includes selecting a location and an unused time slot for the abbreviated MRI procedure available between scheduled diagnostic MRI procedures at one of a predetermined set of existing procedure facilities affiliated with the scheduling service as a function of location and time parameters of a user and an availability of the predetermined set of procedure facilities.

2. The method according to claim 1, wherein the abbreviated MRI procedure designed for an asymptomatic individual includes a T2 type MRI scan.

3. The method according to claim 1, wherein the abbreviated MRI procedure designed for an asymptomatic individual is to be performed on a brain of the user of the scheduling service.

4. The method according to claim 1, wherein the contacting includes a computer network connection of the user to the scheduling service.

5. The method according to claim 1, further comprising determining a result of the abbreviated MRI procedure designed for an asymptomatic individual.
6. The method according to claim 5, wherein the result is determined by a radiologist associated with the procedure facility performing the abbreviated MRI procedure designed for an asymptomatic individual.
7. The method according to claim 6, further comprising storing the result by the scheduling service.
8. The method according to claim 2, wherein the predetermined set of existing procedure facilities include a set of existing MRI facilities.
9. The method according to claim 2, wherein the contacting includes contacting the scheduling service via one of a computer network connection and a voice connection.
10. The method according to claim 9, wherein the computer network connection includes an Internet connection via a web browser.

11. The method according to claim 10, wherein the determining includes presenting at least one web page screen to the user requesting predetermined user personal and medical information.

12. The method according to claim 11, wherein determining if the abbreviated MRI procedure can be authorized is performed as a function of the user's predetermined user personal and medical information.

13. A system for health care screening, comprising: a central processing unit; and a memory coupled to the central processing unit; wherein computer program means stored in the memory are executed by the central processing unit, the executed computer program means receiving a request for an abbreviated MRI-based health care screening procedure designed for an asymptomatic individual, determining if the abbreviated MRI-based health care screening procedure can be authorized, scheduling the abbreviated MRI-based health care screening procedure with a provider capable of performing the abbreviated MRI-based health care screening, wherein the scheduling includes selecting a location and an unused time slot for the health care screening procedure available between scheduled diagnostic MRI procedures at one of a predetermined set of existing procedure facilities affiliated with the scheduling service as a function of location and time parameters of a user and an availability of the predetermined set of procedure facilities.

14. The system according to claim 13, wherein the receiving includes receiving a request via a computer network connection of the user to the scheduling service.

15. The system according to claim 14, wherein the computer network connection includes an Internet connection via a web browser.

16. The system according to claim 14, wherein the determining includes presenting at least one web page screen to the user requesting predetermined user personal and medical information.

17. The method according to claim 16, wherein determining if the abbreviated MRI-based health care screening procedure can be authorized is performed as a function of the user's predetermined personal and medical information.

18. The system according to claim 13, wherein the abbreviated MRI-based health care screening procedure includes a T2 type MRI scan.

19. The system according to claim 18, wherein the abbreviated MRI-based health care screening procedure is performed on a brain of a user.

20. An article of manufacture, comprising: a computer usable medium having computer readable code means embodied therein for causing a scheduling of an abbreviated MRI-based health care screening procedure designed for an asymptomatic individual, the computer readable program code means in said article of manufacture including computer readable program means for causing a computer to receive a request for the abbreviated MRI-based health care screening procedure designed for an asymptomatic individual, computer readable program means for causing the computer to determine if the abbreviated MRI-based health care screening procedure can be authorized, computer readable program means for causing the computer to schedule the abbreviated MRI-based health care screening procedure with a provider capable of performing the abbreviated MRI-based health care screening procedure, wherein the scheduling includes selecting a location and an unused time slot for the health care screening procedure available between scheduled diagnostic MRI procedures at one of a predetermined set of existing procedure facilities affiliated with the scheduling service as a function of location and time parameters of a user and an availability of the predetermined set of procedure facilities.

EVIDENCE APPENDIX

None.